THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (SHRI A. RAJA): (a) Under the Drugs and Cosmetics Act, 1940 any person or any recognized consumer associations, whether such person is a member of that association or not, shall on application in the prescribed manner and on payment of the prescribed fee, be entitled to submit for test or analysis to a Government Analyst any drug or cosmetic purchased by him or it and to receive a report of such test or analysis signed by the Government Analyst.

(b) The Laboratories at Delhi, Hyderabad and Kolkata are as under:—

(1) Combined Food and Drugs Laboratory, A-2, Lawrence Road, Delhi-35.

(2) Drugs Control Lab., Drugs Control Admn., Vengal Rao Nagar Hyderabad-500 038 (A.P.)

(3) The Central Drugs Laboratory, 3 Kyd. Street, Kolkata.

(4) State Drugs Control & Research Laboratory, No. 2, Convent Lane, Kolkata-700 015.

(c) Even though, it is difficult to differential physically between the false and genuine product, close examination and comparison of the labelling of the medicine or of the formulation with geniue product could reveal the difference.

Sale of harmful drugs

56. SHRI MANOJ BHATTACHARYA: Will the Minister of HEALTH AND FAMILY WELFARE be plesed to state:

(a) whether it is a fact that a number of medicines containing harmful drug formulations which have been banned abroad are being freely sold in the country;

(b) if so, the details thereof and the reasons therefor;

(c) the steps taken, if any, during the last three years to ban such medicines; and

(d) the other measures being contemplated to eliminate the sale of these harmful medicines?

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (SHRI A. RAJA): (a) and (b) Certain drugs and formulations banned in some countries at times continue to be marketed in other countries because the decision to do so is normally based on risk assessment process which is influenced by a number of factors such as disease pattern in a country, the varying reactions of certain ethnic groups in a given population to the drug and the availability of safer substitutes as well as the cost factor involved in the treatment of a particular disease. There is also the overall awareness that administration of any drug is not absolutely free from side effects or adverse reactions in a statistically insignificant minority of the population.

The risk assessment of an approved drug begins with information about its review, restriction, discontinuation or ban in any country. The evaluation of the data is done in consultation with leading experts in the given specialization. Based on their advice, the matter is placed before the Drug Technical Advisory Board (DTAB), a statutory body which comprises of representatives from the medical profession, the State drug enforcement authorities, experts institutions agencies that advise Government on tehnical issues related to the implementation of the Drugs and Cosmetics Act 1940, like whether or not to ban or phase out an existing drug.

Our of 46 drugs previously reported by the WHO as banned in some countries, 26 drugs were never marketed in this country. Of the remaining 20 drugs, 13 drugs have been discontinued based on expert evalution and recommendation of the DTAB. While 7 drugs have been allowed to be continued to be marketed subject to cautionary statement and contra indications being given on the label and in some cases on the package insert.

(c) and (d) An Expert Committee (Sub-Committee of Drugs Technical Advisory Board) examines the use of drug formulations reported to be withdrawn in certain countries on the basis of technical data available on the formulation. Its recommendations are then considered by DTAB. In case the drug formulation is found to be harmful or irrational, its manufacutre and sale is prohibited in the country through a Gazette Notification. The examination of the rationality of drug formulation banned in other countries and permitted to be marketed in India is a continuous process.

72 categories of drug formulations have so far been prohibited by the Central Government as these were considered irrational or hazardous. A Statment giving the list of drugs prohibited for manufacture, sale and distribution in the last 3 years is given as under.

Statement

Drugs prohibited for manufacture, sale and distribution during the years 2000 to 2002.

1. Fixed dose combination of Diazepam and Diphenhydramine Hydrochloride.
2. Fixed dose combination of Metoclopramide with other drugs except combination of Metoclopramide with Aspirin/Paracetamol.
3. Fixed dose combination of Vitamin B1, Vitamin B6 and Vitamin B12 for human use.
4. Fixed dose combination of hemoglobin in any form (natural or synthetic).
5. Fixed dose combination of Pancreatin or Pancrelipase containing amylase, protease and lipase with any other enzyme.
6. Fixed dose combination of Nitrofurantoin and Trimethoprim.
7. Fixed dose combination of Phenobarbitone with any anti-asthamatic drugs.
8. Fixed dose combination of Phenobarbitone with Hysocin and/or Hyoscyamine.
9. Fixed dose combination of Phenobarbitone with Ergotamine and/or Belladona.
10. Fixed dose combination of Haloperidol with any anti-cholingeric agent including Propentheline Bromide.
11. Fixed dose combination of Nalidixic acid with any anti-amoebics including Metronidazole.

12. Fixed dose combination of Loperamide Hydrochloride with Furazolidone.

13. Fixed dose combination of Cyproheptadine with Lysine or Peptone.

Deaths due to AIDS in NER

57. SHRI H.K. JAVARE GOWDA: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether it is a fact that hundreds of people are dying of AIDS in North-Eastern Region in the country;

(b) if so, the details of deaths for the last three years;

(c) whether Government will propose special package for combating AIDS menace in the North-Eastern Region; and

(d) if so, the details thereof?

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (SHRI A. RAJA): (a) and (b) No, Sir.

As per the reports received from States in North-Eastern Region, 144 AIDS cases have died in the region during last three years. A statement of reported AIDS deaths in North-Eastern States during last three years is enclosed (*See below*).

(c) and (d) The risk of HIV transmission among injecting drug users increases on account of the sharing of injecting equipment without proper and adequate sterilization.

In order to prevent the spread of HIV infection among injecting drug users, the National AIDS Control Organisation has initiated Targetted Intervention projects. At present, 69 such projects are being implemented by NGOs in the States of Arunachal Pradesh, Assam, Manipur, Meghalaya, Nagaland, Sikkim, Mizoram and Tripura.

Safe injecting drug practices are vital and important for the prevention of HIV/AIDS among injecting drug users in the North East, to prevent the transmission of HIV, which includes; (i) peer education and counseling, (ii) syringes/needle exchange;